K051037

JUN 28 2005

510(k) Summary of Safety and Effectiveness

Per Title 21 CFR 807 . 92, the following is the 510(k) Summary for the ImageQube manufactured and marketed by Intuitive Imaging Informatics, LLC under the trade-name .

(1) SUBMITTER:

Intuitive Imaging Informatics, LLC
30 Hackamore Lane Suite 4
Bell Canyon, CA 91307-1061

818-347-8919 (phone)
818-347-8909 (fax)

CONTACT:

Donald Mundt
Manager, Regulatory Affairs
Intuitive Imaging Informatics, LLC
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Bell Canyon, CA 91307-1061

818-347-8919 (phone)
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SUBMISSION DATE: 15 January 2005

(2) DEVICE NAME:

TRADE NAME: **ImageQube**

COMMON NAME: Image Processing system

CLASSIFICATION NAME: (per regulation 21 CFR 892.2050) (Class II device)
Picture Archiving and Communication System (PACS)

PRODUCT CODE: LLZ

(3) PREDICATE DEVICE:

Intuitive Imaging Informatics claims Substantial Equivalence to the following device:

Manufacturer	Trade Name	510(k) Number	Decision Date
Amicas Inc.	Amicas Light Beam Workstation	K022970	11-22-02

(4) DEVICE DESCRIPTION:

ImageQube is designed for use by a physician or other medical professionals in the acquisition of medical images and demographic detail from all institutional imaging modalities, including CT, CR, MRI, NM, DR, US, Angio, nuclear medicine, and secondary capture devices such as film

digitizers or other imaging sources.. The acquired medical images and demographic information may be displayed, processed, reviewed, sent to and retrieved by radiologists at remote sites, stored, archived or printed. Multi-planar Reconstruction (MPR), Anatomic Triangulation (AT) and 3D display are optionally available.

(5) INTENDED USE OF DEVICE

The ImageQube PACS is intended for use by a physician or other medical professionals in the acquisition of medical images and demographic detail from all institutional imaging modalities, including CT, MRI, NM, DR, US, nuclear medicine, Angio and secondary capture devices such as film digitizers or other imaging sources. The acquired medical images and demographic information may be displayed, processed, reviewed optionally utilizing Multi-planar Reconstruction (MPR), Anatomic Triangulation (AT) and 3D display, sent to and retrieved by radiologists at remote sites, stored, archived or printed.

(6) SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE

The proposed ImageQube, with MPR, AT options, and the predicate device Light Beam are both software suites that process DICOM compliant images and provide a standard set of features pertaining to image processing, archiving and networking. The image manipulation tools and storage techniques are essentially comparable. Workstations are technologically the same with some differences in media type for archival storage. Compression algorithms are different but accomplish the same results. Both products operate on commercially available equipment and are available as either a hardware/software package or software only.

Feature	I^3 ImageQube	Amicas Light Beam Workstation
Multimedia Enterprise Distribution of images and data via Internet or Intranet	Y	Y
Automatically receive DICOM images from any Imaging Acquisition Device	Y	Y
Inter-vendor communication		
Receive RIS from HL7 compliant systems	Y	Y
DICOM	Y	Y
IHE	Y	Y
Image Server API	IQViewer	LightView
Secure Web Based Administration	Y	
Maximum Intensity Projection (MIP)	N	Y
Cross Sectional Viewing	Y	Y
Plain Film Studies	Y	Y
Individual User Templates	Y	Y
Image review and manipulation tools	Y	Y
Image Measurement tools	Y	Y
Transmission	Lurawave®	JPEG2000

(7) SAFETY

The potential hazards are identified and controlled by a risk management plan. The plan consists of a risk management summary, a software development and validation process, a software verification plan and conformance to Federal Regulations and Industry Standards.

(8) CONCLUSION

The ImageQube DICOM compliant imaging system acquires, processes, archives and distributes images over the Internet utilizing similar techniques and functions as the predicate device Amicas Light Beam Workstation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2005

Intuitive Imaging Informatics, LLC
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K051037
Trade/Device Name: Intuitive Imaging Informatics ImageQube
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 14, 2005
Received: June 15, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K051037

Device Name: Intuitive Imaging Informatics ImageQube

Indications for Use

ImageQube is intended for use by a physician or other medical professionals in the acquisition of medical images and demographic detail from all institutional imaging modalities, including CT, MRI, NM, DR, US, nuclear medicine, Angio and secondary capture devices such as film digitizers or other imaging sources. The ImageQube Web system is designed for acquisition, storage, and distribution of all modalities. Device is also designed for primary interpretation of all modalities except mammography. Device is not to be used for primary imaging diagnosis in mammography and will be conspicuously labeled as such during display of mammography images. The acquired medical images and demographic information may be displayed, processed, reviewed optionally utilizing Rational Imaging PACS Multi-planar Reconstruction (MPR), Anatomic Triangulation (AT) and 3D display, sent to and retrieved by radiologists at remote sites, stored, archived or printed.

Prescription Use X AND/OR Over-The Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051037